

REMARKS

Following entry of the foregoing amendments, claims 35 to 37 and 41 to 43 will be pending in the application. Claims 32 to 34 and 38 to 40 have been canceled, and claims 37 and 43 have been amended herein, without prejudice. No new claims have been added. Applicants respectfully request reconsideration of the rejections of record in view of the foregoing amendments and the following remarks.

Alleged Anticipation

Claims 35 to 37 and 41 to 43 have been rejected under 35 U.S.C. § 102(a) as allegedly anticipated by published PCT application number WO 96/12477 ("the Rantala application"). Applicants respectfully request reconsideration and withdrawal of the rejection because the Rantala application fails to teach every limitation of these claims.

The pending claims, for example, recite methods that comprise, *inter alia*, administering oxybutynin to a patient such that the oxybutynin/desethyl metabolite ratio in the plasma of the patient is greater than about 0.36, or is between about 0.36 to about 0.41.

The Rantala application, however, does not describe such methods. Figures 1 and 2 of the Rantala application are said to show the concentration of oxybutynin and N-desethyl-oxybutynin, respectively, present in the blood of patients following administration of a 10 mg tablet of controlled-release oxybutynin chloride.¹ As can be seen by comparing Figures 1 and 2, the ratio of oxybutynin to the N-desethyl metabolite in the patients' blood was not greater than about 0.36, and was not between about 0.36 to about 0.41. The Rantala application, accordingly, does not describe the claimed subject matter.

Although the Office Action asserts that the Rantala application describes experiments in which serum levels of oxybutynin and N-desethyl oxybutynin were from 0.2 ng/ml to 30 ng/ml and 2.5 ng/ml to 150 ng/ml, respectively,² the application contains no such teaching. Rather, the application simply states that the *detector* that Rantala, *et al.*, used to generate the data presented in Figures 1 and 2 operated linearly when the concentrations of oxybutynin

¹ page 12, lines 7 to 12 and page 10, lines 3 to 12.

² Office Action dated December 5, 2005, page 4.

and N-desethyl oxybutynin were from 0.2 ng/ml to 30 ng/ml and 2.5 ng/ml to 150 ng/ml, respectively.³

Since the Rantala application does not teach or suggest the claimed methods, Applicants request that the rejection for alleged anticipation be withdrawn.

Alleged Double Patenting

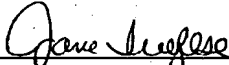
Claims 32 to 43 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 14 and 15 of U.S. Patent No. 6,262,115 ("the 115 patent"). Although Applicants question whether there has been an adequate showing that those of ordinary skill in the art would have found the pending claims to have been obvious in view of the claims of the referenced patent, they nonetheless submit herewith the requested terminal disclaimer. This is being done solely in an attempt to advance prosecution of this patent application, and should not be construed to constitute an acknowledgment of obviousness or any other substantive relationship among the involved patent claims.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable action is respectfully requested.

Respectfully Submitted,

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Jane E. Inglese, Ph.D.
Registration No. 48,444

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

³ Rantala application, page 11, lines 20-29.